

REMARKS

The Examiner's action dated March 17, 2006, has been received, and its contents carefully noted.

All of the cited references deal with generating a temperature gradient that is perpendicular to the skin surface (heating the underlying dermis to a higher temperature than the overlying epidermis). In contrast, the present application deals with a temperature gradient parallel to the skin surface (bringing a skin surface target to a temperature that is 5°C above that of the surrounding skin surface).

Claim 1 originally defined this distinction by referring to a "skin area containing at least a portion of the target". The definition of "target" at page 1, lines 4-5 of the specification clearly indicates that this is at the skin surface. Moreover, each of the original independent claims referred to "skin surrounding the target". Such skin must of necessity be at the skin surface; in fact, skin is, by definition, the external covering of a human being. Original claim 6 expressly refers to the surrounding skin surface.

Since it appears that the significance of this basic aspect of the present invention was not clearly appreciated,

the claims have been amended to refer more specifically to the skin surface.

Therefore, all of the rejections are traversed for the reason that none of them, nor any reasonable combination thereof, discloses or suggests creating temperature difference between different regions of a skin surface. Furthermore, the reason for presenting four different rejections of the same claims is not understood; if any one rejection is sound, the others are unnecessary. Such multiple rejections simply place an undue burden on applicant.

None of the cited references makes any mention whatsoever of generating a temperature gradient parallel to the skin surface and the supposition that the methods and systems of the applied references would inherently create a temperature difference of at least 5°C parallel to the skin surface is unfounded.

Considering, first of all, US Patent 6,053,909 to Shadduck, this patent uses an applicator having two RF electrodes 40 (see Fig. 4) between which is a light guide 30 that directs light to the skin surface. While the Examiner appears to be correct that the flux range of light energy specified in Claim 8 of the application is mentioned in

Shadduck (col. 9 lines 15-22), Shadduck specifically mentions that a wavelength is used that is selectively absorbed by water in order to selectively heat the collagen-containing dermis. See for example the paragraph bridging cols. 5 and 6. There it specifically states that the goal is to "photosensitize the sub surface tissue" (col. 5 line 62) (i.e. a gradient perpendicular to the skin surface) and the preferable wavelength is "from about 1.30 to 3.00 microns" (col. 6 line 3), i.e. in the infrared region and well below the visible range. In order to heat a target to 5°C above the surrounding skin surface, it would be necessary to apply light energy having a wavelength that is selectively absorbed by the epidermis, which means light in the visible range. Thus, even if the light source of Shadduck had the same energy flux as recited in the present application, it would not create the specified temperature gradient between the target and the surrounding skin because the energy supplied by Shadduck's light source is preferentially absorbed in the dermis and not in the epidermis.

Turning now to Knowlton (US 5,755,753), in col. 3 lines 25-30, Knowlton states that a gradient is generated in which the "underlying desired layers" are brought to a

temperature that is 30° to 80° above the skin surface (*i.e.* gradient perpendicular to the surface). The "target" to which the Examiner refers is located below the skin surface, and not in "a skin surface area located between the electrodes" as now recited in Claim 1 of the application. Moreover, the system and method of Knowlton cools the entire skin surface, possibly except for the region of contact of the electrodes. In particular, Knowlton cools the skin surface in the area between the electrodes, together with the skin surface outside this area, so that a temperature gradient of at least 5°C parallel to the skin surface clearly would not be generated.

The above remarks relating to Shadduck also overcome the Section 103 rejection based on a combination of Taylor and Shadduck. As regards the Examiner's assertion that Taylor "fails to specifically disclose a temperature gradient of at least 5°C", it must be pointed out that Taylor, in fact, totally fails to disclose any temperature gradient, or difference, along the skin surface.

In addition, it must be noted that Taylor also uses light in the range of 1.06 to 10.6 microns, which is again the infrared region (col. 6 lines 55-56). As explained in the Knowlton patent, this would generate a temperature gradient

perpendicular to the surface and not parallel to the skin surface because light in that wavelength range is preferentially absorbed by the dermis and not the epidermis.

The above remarks relating to the Knowlton publication also overcome the Section 103 rejection based on a combination of Stern and Knowlton, particularly in view of the above-discussed deficiencies of Knowlton. In addition, it should be noted that the Stern patent also relates to creating a temperature gradient perpendicular to the skin surface. At columns 11 and 12, to which the Examiner refers, it is stated that the system *"can be configured to pre-cool the surface layers of the target tissue"* (col. 12 lines 5-6) and that *"pre-cooling allows the achievement of a desired tissue depth thermal profile"*. It would be logical to assume that cooling the surface layers of the target tissue would place the target tissue at a lower temperature than surrounding tissue. Hence a combination of these two references would not generate the claimed temperature difference parallel to the skin surface.

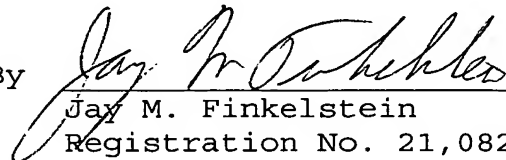
In view of the foregoing, it is requested that all of the prior art rejections be reconsider and withdrawn, that claims 1-14 be allowed and that the application be found in allowable condition.

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If the above amendment should not now place the application in condition for allowance, the Examiner is invited to call undersigned counsel to resolve any remaining issues.

Respectfully submitted,

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